TESTIMONY OF

THOMAS HAMILTON
DIRECTOR
SURVEY & CERTIFICATION GROUP
CENTER FOR MEDICAID AND STATE OPERATIONS
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON
CLINICAL LABORATORY QUALITY

BEFORE THE
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES
OF THE
HOUSE COMMITTEE ON GOVERNMENT REFORM

June 27, 2006

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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Chairman Souder, Representative Cummings, distinguished members of the Committee: I thank you for your invitation to appear here this morning to discuss efforts to ensure quality testing results in all laboratories in the United States. The Centers for Medicare & Medicaid Services (CMS) works with a number of different entities, including state government agencies, professional associations and independent survey groups, to ensure that entities receiving Medicare payments comply with established conditions of participation for their provider type and that all laboratories in the U.S. meet Clinical Laboratory Improvement Amendments (CLIA) standards. This morning I would like to first discuss CMS' general efforts at ensuring laboratory quality and then the specifics of the GAO Report: "Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened."

CLIA Background

In 1988, Congressional hearings concerning deaths of women from erroneously read Pap smears, and the proliferation of bench top laboratory technology into non-traditional testing sites, led to passage of CLIA. CLIA established nationally uniform quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of the setting in which the test was performed. A laboratory subject to CLIA is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of a disease or

impairment, or to assess the patient's health. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Final CLIA regulations were published on February 28, 1992 and are based (as required by statute) on the complexity of the test method; thus, the more complicated the test, the more stringent the compliance and oversight requirements. Three categories of tests have been established: waived; moderate complexity, including the subcategory of provider-performed microscopy (PPM); and high complexity. CLIA specifies detailed quality standards for the latter two categories. Laboratories performing only waived tests must enroll in CLIA, pay the applicable fee and follow manufacturers' testing instructions.

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, and approving entities that test laboratory proficiency, accrediting organizations and exempt states with appropriate requirements. The Centers for Disease Control and Prevention (CDC) is responsible for CLIA research studies, convening the Clinical Laboratory Improvement Advisory Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS. The Food and Drug Administration (FDA) is responsible for test categorization.

Laboratory Enrollment and Performance Standards

To enroll in the CLIA program, laboratories must register by completing an application, pay fees, be surveyed, if applicable, and receive a CLIA certificate. CLIA fees are based on the certificate requested by the laboratory (that is, waived, provider performed microscopy (PPM), accreditation, or compliance) and, for moderate and high complexity laboratories, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificate as they aren't subject to routine inspections, unless there is a complaint. Laboratories that must be surveyed routinely (i.e., those performing moderate and/or high complexity testing) may choose whether they wish to be surveyed by CMS or by a private accrediting organization. The biennial CMS survey process is outcome (test result) oriented and

utilizes a quality assurance focus to assess compliance. An educational approach is employed in which the surveyor may provide resources and an explanation of the requirements to the laboratory that allow the laboratory to correct deficiencies prior to imposition of enforcement actions. However, if the laboratory cannot correct the problem(s) within a reasonable amount of time, sanctions are imposed that are commensurate with the history, seriousness and pervasiveness of the deficiencies.

Labs subject to routine biennial surveys must comply with a number of CLIA requirements, including:

- Personnel: CLIA sets minimum qualifications, experience and training requirements for all persons performing or supervising moderate or high complexity lab tests. These individuals must also meet specific responsibilities that correspond to all of the CLIA quality standards.
- Proficiency testing: Many labs must also participate in an approved proficiency testing program that provides an external evaluation of the accuracy of the lab's test results. Under this requirement, three times per year, labs purchase samples from an external source (the proficiency testing provider), whose characteristics are not disclosed to the lab. The lab tests the samples along with their routine patient testing and the results are returned to the testing provider to be graded. If the lab passes, they have met the CLIA standard. The results of proficiency testing for all labs in CLIA are transmitted to CMS and are routinely monitored and maintained in a database. If a laboratory repeatedly fails proficiency testing during successive testing challenges, then action is taken to limit the laboratory's ability to continue performing the test(s). Proficiency testing providers are private companies, or state lab departments, that must meet certain CLIA requirements to provide testing samples to labs, and are approved by CMS annually.
- Quality control: Labs must have a process for monitoring personnel, testing equipment and the lab's environment to ensure proper operation and accurate results each day.
- Quality assessment: Labs must have and follow a plan to monitor, on an ongoing basis, the overall operation of the laboratory, provide communications, and resolve problems that affect the quality of their testing.

- Cytology testing: CLIA sets special rules for cytology testing including workload limits, individualized proficiency testing, personnel standards, and quality control.
- The lab must maintain a recordkeeping system for the entire testing process.

Data show that these regulations are helping to improve testing quality. Since CLIA was implemented in 1992, quality deficiencies cited against clinical labs have decreased significantly. The first onsite surveys of labs revealed that up to 35 percent of labs had quality issues. Currently less than 7 percent of 11,000 labs surveyed by CMS in a year have quality problems. We believe that our educational rather than punitive approach has facilitated improvement in lab quality. Data from our Survey Evaluation Form show that most laboratories respond very positively to the educational, information-sharing approach to oversight and correct their problems prior to imposition of enforcement actions. The quality assurance approach encourages labs to develop a plan to monitor their entire operation to identify and resolve their quality-related problems on an ongoing basis. Survey data and proficiency testing data reflect improvement in lab performance over time, thus demonstrating labs' accountability in knowing the regulatory requirements and preventing and correcting identified issues. When CMS finds problems during the survey, the lab is generally provided an opportunity to correct these problems prior to enforcement actions, unless there is actual or potential harm to patient safety or there are recurring deficiencies. Over the past five years, CMS has proposed enforcement action in 5,361 cases, and carried out such action in 395 instances.

Oversight and Surveys

CMS contracts with State Departments of Health to perform lab surveys. CMS' objective in developing an outcome oriented survey process is primarily to determine the laboratory's regulatory compliance, but also to assist laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process. The surveyor determines, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel and review of the laboratory's relevant documented records, whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely (quality) test results. The surveyor meets the objectives by employing an outcome-

oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory regarding the applicable standards and the way it monitors itself, rather than on a methodical evaluation of every standard level regulatory requirement.

The quality assessment (QA) requirements of the laboratory regulations (42 CFR Part 493, Subpart K) are the appropriate guide that surveyors use for organizing their review. The surveyors select a cross-section of information, tour the facility and observe testing, and review quality records and all aspects of the laboratory's operation to assess its capability to produce quality results as well as its ability to identify and correct problems and communicate with its clients. Emphasis is placed on overall laboratory performance and the structures and processes contributing to the reliability of the testing. Since it would be impossible to review every test and every document in the laboratory, the surveyor reviews the selected cross-section of information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices and solving its problems. The surveyors investigate further any test areas identified as a problem but not addressed by the laboratory's QA program, ensure permanent resolution of previous deficiencies and review any new tests and personnel since the last visit. If the laboratory is failing to monitor (or effectively monitor) its own systems, the surveyor may direct the laboratory to the requirements and the relevant regulatory sections for its particular setting, thereby accomplishing the educational aspect of the survey process.

If, however, problems identified during the survey, or as the result of a complaint, are not remedied in a reasonable amount of time, CMS has authority to impose sanctions against the lab from an array of available actions. These may range from onsite monitoring, fines, or loss of Medicare reimbursement, to revocation of their CLIA certificate, depending on the seriousness and pervasiveness of the problem. Most laboratories correct their problems as a result of the education they receive following the survey, prior to having sanctions imposed. Only about one percent of laboratories surveyed each year have had enforcement actions taken against them. The names of these labs and the laboratory director are compiled annually and this list is placed on the CLIA web site at: www.cms.hhs.gov/clia. The 2005 registry lists 240 entities. The

percentages of each laboratory type experiencing enforcement actions are proportional to the total number of labs of that type enrolled in the CLIA program.

As mentioned previously, labs that are subject to biennial surveys can choose to obtain CLIA certification by the State agency, as an agent of CMS, or by an approved private accreditation organization. Accrediting organizations with standards that are equivalent to, or more stringent than CLIA, currently approved by HHS for this purpose include:

- the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
- the College of American Pathologists (CAP),
- COLA (formerly Commission on Office Laboratory Accreditation);
- the American Association of Blood Banks (AABB);
- the American Society for Histocompatibility and Immunogenetics (ASHI); and
- the American Osteopathic Association (AOA).

States that have lab licensure program standards equivalent to, or stricter than those of CLIA can apply for "approval" or "exemption." Then the labs in those states that meet state licensure requirements are deemed to be in compliance with CLIA. There are currently only two exempt states – New York and Washington. In other states that have a state laboratory licensure program, laboratories within the state must comply with both CLIA and their state requirements.

On an annual basis, CMS, through the state agencies, surveys approximately 2.5 percent of accredited and exempt laboratories using CLIA standards to validate that these laboratories are in compliance with CLIA by meeting the accrediting organization's standards and to ensure that the organization is enforcing its own equivalent standards. After surveying the accrediting organization's laboratories, CMS compares the results of the state survey to the accrediting organization's, to determine the level of disparity. The rate of disparity is the percentage of all sample validation surveys for which a State survey agency finds non-compliance with one or more CLIA conditions and no comparable condition level deficiency was cited by the accreditation organization. As set forth in regulation at 42 CFR 493 Subpart E, an accreditation program with a disparity rate of 20 percent or more is subject to a review to determine if that

organization has adopted and maintains requirements comparable to those of CMS. No accrediting organization has even approached the maximum threshold of 20 percent disparity.

Complaints alleged against accredited laboratories from any source are either addressed by the accrediting organization or by the State agency in conjunction with the CMS Regional Office. CMS has recently implemented an automated complaint tracking system to capture all complaints to ensure timely and complete follow up and investigation. Ultimately the approved accrediting organizations and exempt States will enter their complaint data into this system to provide national data for CMS to monitor for program effectiveness.

CMS Responds to GAO Draft Report

As you are aware, this Subcommittee requested that the GAO assess the effectiveness of CMS' oversight of clinical laboratories, and our enforcement of CLIA. We have been given an opportunity to examine and comment on a draft of that report and I would like to take some time to respond to each of the recommendations the GAO made in that document.

GAO Recommendation #1: *Work with exempt state-programs and accrediting organizations to standardize their categorization and reporting of survey findings in a way that tracks to CLIA inspection requirements and allows for meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.*

CMS Response: We endorse this concept but will be cautious as to its scope. In our experience, a straightforward linkage of accrediting organization requirements to CLIA condition-level requirements is limited by our authority under the statute, and still may not make it fully possible to assess labs in a standardized manner.

First, the law permits each accrediting organization to have different requirements compared to CMS, so long as their requirements are at least equivalent to CMS requirements.

Second, accrediting organization requirements may exceed CMS requirements (so their standard may not have a CMS equivalent).

Third, standardization of requirements does not automatically provide a total picture of the adequacy of an accrediting organization's survey and will not reduce the need for CMS to analyze in-depth those accrediting organization surveys that are subject to validation review[1].

Fourth, after multiple review cycles, CMS has verified that the accrediting organization's published standards are at least equivalent to, if not more stringent than the CLIA regulations. We believe the more important issue in accrediting organization oversight is the accrediting organization's *enforcement* of their standards. Demonstrating that an accrediting organization is enforcing its standards through comprehensive policies, procedures and internal monitoring processes is vital to the effectiveness of a program. An accrediting organization can have the highest standards, but if not enforced appropriately, these standards hold little value in ensuring laboratory quality. Toward that end, CMS has re-focused its approval and oversight of accrediting organizations to concentrate on outcomes. This re-focusing is not only a more efficient use of CMS resources, but also a more effective approach overall in overseeing accrediting organizations.

To supplement the validations and other information about accrediting organizations, CMS, through the Partners for Laboratory Oversight process, has convened a workgroup of accrediting

[1] For example, we might equate an accrediting organization's requirement for proficiency testing enrollment with CMS' CLIA condition-level requirement for proficiency testing enrollment. Beneath the surface, however, we must be aware that proficiency testing enrollment applies to the laboratory's enrollment in proficiency testing for a great many potential analytes. If an accrediting organization-to-CLIA linkage is based only on lack of enrollment in testing, regardless of how many analytes were omitted, the assessment of quality would be woefully incomplete. Such an incomplete picture of quality would represent an inadequate assessment of quality since it would not capture all the serious deficiencies that have occurred. In our CLIA validation review of accreditation organizations, a CMS team manually reviews and compares the entire narrative findings of the CLIA validation inspections to those of the accrediting organization inspections. The entire narratives are compared and not limited to whether or not the accrediting organization found a deficiency in proficiency testing enrollment. Otherwise, the picture would be incomplete and our review would be inadequate. We need to know more about the analytes involved. If the CLIA validation inspection found that the laboratory failed to enroll in proficiency testing for 2 analytes, e.g., prothrombin time and glucose, but the accrediting organization inspection found that the laboratory failed to enroll in proficiency testing for only 1 of those 2 analytes, prothrombin time, the review identifies an inadequacy on the part of the accrediting organization —the accrediting organization inspection has failed to identify a serious flaw in the laboratory's practices that can negatively impact the quality of the laboratory's testing and the outcome can be death. In a worst case scenario, the laboratory's lack of enrollment in proficiency testing for the analyte glucose can result in inaccurate and unreliable testing results, which could affect the health status of a diabetic patient. The flawed testing results could directly result in patient fatality from diabetic shock. If the laboratory performs thousands of tests each year under those circumstances, thousands of patients are at risk.

organizations and CMS representatives to develop data-driven performance indicators similar to the State Agency Performance Review (SAPR) program that CMS utilizes to monitor State agency performance of CLIA responsibilities and adherence to policies. The accrediting organization indicators would monitor routinely, for example, whether biennial surveys were conducted timely, and whether laboratories that failed proficiency testing or incurred serious deficiencies corrected their problems promptly or had sanctions imposed. The Partners for Laboratory Oversight effort engages an exceptional collection of expertise and experience in laboratory oversight. By organizing the "best of the best" in a collaborative endeavor involving all accrediting organizations, we hope that accrediting organizations will make further improvements as well as advance the state of the art for laboratory quality.

CMS Action:

1(a) Categorization of Findings: CMS will work with exempt state-programs and accrediting organizations to promote greater standardization of categorizing and reporting survey findings in a way that enables improved tracking to CLIA inspection requirements and allows for more meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.

GAO Recommendation #2: *Ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS' policy for advance notice provided by state survey agencies.*

CMS Response: We agree. CMS will require any accrediting organization using announced surveys to reduce its lead time to be consistent with CMS policy governing actions of State survey agencies.

CMS Action:

2(a) Advance Notice in Small Labs: CMS will ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS' policy for advance notice provided by State survey agencies.

2(b) Consistency: CMS will work with accrediting organizations and State survey agencies to promote unannounced surveys in larger labs and achieve greater consistency among all oversight organizations.

GAO Recommendation #3*: Ensure that regulation of labs is the primary goal of survey organizations and that education to improve lab quality does not preclude the identification and reporting of deficiencies that affect lab testing quality.*

CMS Response: We agree that education to improve lab quality should never preclude the identification of deficiencies that affect lab testing quality, and that regulation of labs is the primary goal of survey organizations. In the case of significant new requirements, and only within certain areas for the time period specified by CMS, the educational approach may include the possibility of identified deficiencies being communicated to laboratories without a concomitant citation. Currently, such allowance primarily applies to two situations:

- Quality control requirements that were new in the 2003 regulation for labs conducting moderate complexity testing;
- Cytology proficiency testing that was newly implemented on a national basis in 2005.

For the reasons explained previously, we do not anticipate a change in this policy.

CMS Action:

3(a) Consistency Action Plan: CMS will ensure that a CMS Consistency Workgroup comprised of Regional Office and Central Office CLIA staff formulates an action plan to increase consistency.

3(b) Guidance: CMS will develop protocols or refinements to surveyor guidance to ensure an appropriate balance between the enforcement and educational functions of the survey process.

3(c) Training: CMS will provide additional training for surveyors and management on the differences between the "educational approach" and the "outcome oriented survey process", including concentrated training on which survey findings require citation without any variation.

3(d) Performance & Consistency Review: CMS will ensure Central and Regional Office data review of key identified data sets, on a periodic basis, to determine if observed variations are truly significant and to identify any significant trends. This increased communication between Central Office, Regional Offices, & State agencies as they work to explain and understand the variations will lead to decreased variability and enhanced consistency over time.

GAO Recommendation #4: *Impose appropriate sanctions on labs with consecutive condition-level deficiencies in the same requirements.*

CMS Response: This recommendation is already CMS policy; the issue is our approach to implementation of the policy. CMS' policy of progressive enforcement involves the imposition of sanctions for laboratories failing to correct deficiencies that impact on the quality of laboratory testing, increasing in severity in the event of continuing failures. By looking only at the category of failure (the "conditions"), however, it is not possible to determine whether a laboratory has consecutively failed in the same requirement.

For example, the laboratory could fail in proficiency testing in one year for neonatal testing, and fail in proficiency testing in a completely different division of the laboratory the next year (e.g., virology). In regard to laboratories with consecutive condition-level deficiencies, the data presented by GAO would not permit us to assess whether there is a serious problem because the underlying failures could have been different in the two consecutive surveys for those

laboratories that the GAO included in its report. Nonetheless, we agree that the issue is important and that labs that consistently fail to assure quality must be subject to consistently stronger remedial action.

CMS Action:

4(a) Monitoring & Data Analysis: CMS will carefully monitor citations of repeat deficiencies as part of the overall redesign of the CMS information system (converting from the Online Survey and Certification Reporting System (OSCAR) database to the ASPEN information system).

4(b) Follow-up System: CMS will review the data with State survey agencies and accrediting organizations for the purpose of ensuring that the laboratories with true repeat deficiencies have accelerated and progressive enforcement actions imposed, if the deficiencies are not corrected expeditiously and effectively[2].

GAO Recommendation #5*: Require all survey organizations to develop, and require labs to prominently display, posters instructing laboratory workers on how to file anonymous complaints*[3].

CMS Response: Complaints from clients or laboratory workers can be an extremely important vehicle for identifying problems. For that reason, CMS follows up on all complaints. Information about filing complaints has already been included in the updated Surveyor and

[2] CMS provides laboratories with an opportunity to correct its problems prior to the imposition of sanctions. If the problem represents a threat to patient health and safety, then the time frame for correction is either very short or the laboratory is required to cease testing. Most laboratories find the threat of sanctions to be an enormous incentive and quickly correct their problems. The desired outcome in CLIA is regulatory compliance, high quality, and prompt and effective remedy of problems. For CMS certified laboratories, 396 laboratories received a notice of a proposed sanction and of those, 93 failed to take prompt corrective action and had sanctions imposed in 2005. The 2005 Laboratory Registry contains 236 laboratories listed for all oversight entities as having sanctions imposed. The number of cases in which sanctions were threatened is approximately four times the sanction level, indicating that in the vast preponderance of cases the laboratories responded quickly to the potential for sanctions. CMS also assessed $4.4 million in civil monetary penalties.

[3] CMS data consistently indicate approximately 200 complaints alleged per year. This relatively low number may alternatively suggest either that quality is good, or that clients and workers do not know the avenues by which to lodge a complaint.

Laboratory Interpretive Guideline document and most States already have a Hotline for the receipt of complaints.

In March 2006, CMS also implemented a new, more sophisticated data system to receive and track complaints. The system will significantly facilitate State agency documentation and follow-up of complaints to their conclusion.

CMS Action:

5(a) Filing Complaints: CMS will take action to promote greater awareness of the opportunity and methods to file a complaint with CMS, State survey agencies, and accrediting organizations regarding the quality of laboratory services. Such actions may include:

- Providing a complaint filing "fact sheet" and model complaint poster on our website;
- Issuing a CLIA brochure regarding complaint filing;
- Encouraging State agencies and partners to publicize the complaint process through their websites and publications; and
- Working with the laboratory industry to use publications to highlight the importance of complaint filing by laboratory workers to promote laboratory excellence.
- Consideration of requirements for all laboratories to display posters instructing laboratory workers on how to file anonymous complaints.

5(b) Complaint Information Sharing: CMS will work with accrediting organizations and States to increase the sharing of information regarding complaints and complaint investigations.

5(c) Complaint Tracking and Response: CMS will seek to augment its complaint tracking system to build in the capability for accrediting organizations to transmit their complaint data to that system, thereby enabling a national complaint information database

(or repository) for the first time. Along with CMS' monitoring its own follow-ups of complaints, such a system would assist the accrediting organizations to follow up timely on complaints they receive.

GAO Recommendation #6: *Consistent with CLIA, require quarterly proficiency testing, except when technical and scientific considerations suggest that less frequent testing is appropriate for particular examinations or procedures.*

CMS Response: CMS already made this determination. While the public explanation emphasized limiting the burden on laboratories, CMS, in conjunction with the Centers for Disease Control and Prevention, concluded on both technical and scientific grounds that proficiency testing three times per year was appropriate.

GAO Recommendation #7: *Ensure that evaluations of exempt State and accrediting organization inspection requirements take place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA.*

CMS Response: We recognize the need to complete timely reviews. However, we must manage the work within available resources and assessment of priorities. Initially, we deemed accreditation organizations and exempt States for periods of less than 6 years. This allowed us to perform multiple assessments to evaluate their programs and assure their standards were consistently equivalent to those of CLIA. Over the years we have found that the accrediting organizations have been consistent in regard to equivalency of standards. To ensure continued equivalency or more stringent requirements than those of CLIA, we are refocusing our approval process and oversight on evaluating how exempt States and accrediting organizations are enforcing their standards and assessing patient testing outcomes through the validation survey process. We are managing the risk appropriately. For accrediting organizations, we are developing performance measures through our partners, and are using the validation process to monitor the outcomes of their survey processes, as well as CLIA compliance. The CMS-convened Partners' for Laboratory Oversight group has already raised the bar by collaborating to

facilitate increased effectiveness, knowledge and consistency for all participating entities, with the aim of improving their application and assessment of compliance for CLIA purposes**.**

CMS Action:

> **7(a) Timely Review of Accrediting Organization Standards:** CMS will ensure, within available resources and priorities, that evaluation of exempt State and accrediting organization inspection requirements takes place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA.

GAO Recommendation #8: *Ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.*

CMS Response: It is correct that the accreditation organization must submit changes to CMS 30 days prior to their implementation [42 CFR 493.557(a)(13)]. However, the regulatory language does not specify a time period for the review of this information by CMS. Additionally, State exemption has no similar requirement. Since accreditation organizations' requirements may be more stringent than CLIA, changes to requirements do not necessarily impact CLIA equivalency determinations.

The approval of accrediting organizations is only one portion of CMS' oversight responsibilities. While we appreciate the value of timely review, we reserve the right to manage the work within available resources and assessment of priorities. Due to the potential for concerns about accrediting organization performance (versus equivalency of standards), CMS increased the percentage of validation surveys performed per year from an initial 1% to the current level of 2.5%. CMS also receives anecdotal information regarding accrediting organization performance from State agencies and specific concerns through the complaint process.

CMS Action:

8(a) Timely Review of Accrediting Organization Changes: CMS will, with available resources and priorities, ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.

GAO Recommendation #9: *Allow the CLIA program to utilize revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities.*

CMS Response: CMS is fulfilling its statutory responsibilities.

CMS Action:

9(a) CLIA Staffing: CMS continues to consider adjustments to CLIA staffing in CMS Central and Regional Offices to meet statutory requirements and priorities.

GAO Recommendation #10: *Ensure that Federal surveyors validate a sufficient number of inspections conducted by each State survey agency to allow a reasonable estimate of their performance, including a minimum of one independent validation review for each State survey agency surveyor.*

CMS Response:

In its recommendation to perform a sufficient number of surveys "to allow a reasonable estimate of their performance," GAO quotes the CLIA statute (at section 353(e)(2)(D) of the Public Health Service Act), which pertains only to the evaluation of approved laboratory accreditation organizations, not the State agencies. There is no statutory requirement regarding the number of surveys to be performed in each State to assess surveyor competency. Nevertheless, we agree that oversight of State agency and surveyor competency is important and that Federal surveyors

should conduct a sufficient number of Federal Monitoring Surveys to allow for a reasonable estimate of State agency performance. In CY 2004, CMS instituted the CLIA State Agency Performance Review, a more comprehensive State agency oversight mechanism. The CLIA State Agency Performance Review includes indicators that measure the mechanisms for improvement in response to findings of our Federal Monitoring Surveys concerning individual surveyor competency assessments.

Types of Federal Monitoring Surveys include:

> **Comparative.** The Regional Office surveyor(s) survey the laboratory after the State agency surveyor(s). This type of survey (called a "Look-Behind") would be considered by GAO to be an "independent" validation survey.
>
> **Observational.** The Regional Office surveyor accompanies the State agency surveyor(s) during the laboratory survey and interacts as necessary to provide guidance to the State agency surveyor(s) at appropriate times.
>
> **Participatory.** The Regional Office surveyor and State agency surveyor(s) identify deficiencies during the laboratory survey.

The Federal Monitoring Survey is a powerful educational tool for surveyor training. Observational and participatory Federal Monitoring Surveys are balanced by the comparative surveys. We estimate the comparative surveys accounted for about 15% of all CLIA oversight surveys during the period GAO studied.

We agree that the comparative survey or "independent validation review" offers a truer assessment of surveyor competency than the observational or participatory Federal Monitoring Survey, and for that reason continue to have the comparative survey as a tool available to Federal surveyors for their oversight responsibilities. We are convinced that Federal surveyors exercise appropriate judgment as to when to select or not select the comparative survey to fulfill their responsibilities for surveyor competency assessment. One must also consider that comparative

Federal Monitoring surveys can be disruptive to laboratories as they require two separate surveys conducted during different time frames to separately determine laboratory compliance for CLIA.

CMS Action:

10(a) Validating State Agency Performance: CMS will increase its efforts to ensure that the Federal Monitoring Surveys are performed annually in each State in numbers sufficient to allow a reasonable estimate of State agency performance, including increasing the number of "independent" reviews.

10(b) Independent Validation Review: CMS will ensure that at least one comparative Federal Monitoring Survey is performed for each surveyor every year.

10(c) Strengthen Training: CMS will strengthen its training focus and application of the outcome-oriented approach to surveying for laboratory compliance with 42 CFR §493 by incorporating additional specific examples and case studies of deficiencies that demonstrate non-compliance in current and future training of laboratory surveyors.

GAO Recommendation #11: *Require that almost all validation reviews of each accrediting organizations' surveys be an independent assessment of performance.*

CMS Response: We reviewed the statistics provided by GAO regarding the numbers of validation surveys performed simultaneously with the laboratory accreditation organizations, as well as our statistics regarding validation surveys. The numbers given for CAP (11%), COLA (9%) and JCAHO (33%) equate to the numbers of simultaneous validation surveys per year for each organization that are shown here in Figure 1.

FIGURE 1: SIMULTANEOUS VALIDATION SURVEYS (Annual Nationwide Data)

Accrediting Organization	Number
CAP	9
COLA	15
JCAHO	23
TOTAL	**47**

Forty-seven is consistent with the number historically recounted by the staff in the CMS regional offices that authorize the validation surveys—an average of about 1 simultaneous validation survey per State per year. It is also consistent with statistics in the CLIA data system for calendar year 2005 (45 simultaneous validation surveys).

The number of validation surveys performed nationwide has increased in recent years to almost 400 validation surveys to ensure that CMS is adequately overseeing accrediting organization performance. At the present level of 1 simultaneous validation survey per State, simultaneous validation surveys constitute about 12 percent of the total number of validation surveys performed. Conversely, about 88 percent of the total validation surveys are performed independently, which equates to the recommendation that almost all validation surveys be an independent assessment of performance. We believe 12-15% is a reasonable proportion to reserve for the opportunities afforded by simultaneous validation surveys, such as:

- promoting understanding of each other's programs;
- sharing of best practices; and
- fostering improvements in accreditation organizations' survey processes.

CMS Action:

11(a) Ensure Validation Surveys: CMS will continue to monitor and ensure that the vast preponderance of validation surveys for accrediting organizations takes the form of independent assessments.

GAO Recommendation #12: *Collect and routinely review standardized survey findings and other available information for all survey organizations to help ensure that CLIA requirements are being enforced and to monitor the performance of each organization.*

CMS Response: We strongly endorse the value of collecting and reviewing survey findings and other available information to monitor, sustain, and improve performance. For this reason we instituted standardized mechanisms for State survey agency performance through the State Agency Performance Review (SAPR) protocols. Those protocols utilize standard indicators of

performance and data. More recently we initiated development of a similar system for application to the performance of accrediting organizations. We believe that the accrediting organization Performance Measures under development will effectively enhance current methods to fulfill our oversight responsibilities for accrediting organizations.

With regard to the "standardized" aspect of this recommendation, we will put emphasis on improving our methods of standardizing interpretations of survey outcomes, even though the standards of each accrediting organization may be different[4].

CMS Action:

12(a) Collection & Review of Accrediting Organization Survey Findings: CMS will explore methods to expand its collection, review, and analysis of survey findings and the follow-up actions of accrediting organizations in order to monitor, sustain and improve performance of accrediting organizations.

GAO Recommendation #13: *Establish an enforcement database to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation.*

CMS Response: We agree that laboratories losing accreditation due to CLIA quality issues require close attention to ensure they are not erroneously deemed CLIA compliant. Our development efforts for enforcement management, and planned future system enhancements,

[4] The CLIA regulations do not require that an accreditation organization's or exempt State's standards be the same as CLIA. Rather, the accreditation organization and exempt State's requirements, taken as a whole, must be equivalent to or more stringent than those of CLIA. The majority of the deemed organizations and exempt States' requirements are at a level that elevates the quality of testing and the standard of practice. CLIA, on the other hand, represents minimum requirements, and is sometimes less rigorous than the routine standard of clinical laboratory practice.

Because their standards can be more stringent than CLIA, the accrediting organizations and exempt States can hold the labs to higher quality requirements. For example, CAP requires proficiency testing for all analytes, not just those that are specified at Subpart I, and the JCAHO has quality standards for waived tests. Standardization would make our reviews easier, but would weaken the accreditation organization standards that are more stringent than CLIA, restrain marketplace-enriching standard development, and change their unique corporate identity and organizational autonomy.

will assist us in tracking and monitoring such cases. We will also be working closely with our state agencies, regional offices and accreditation organizations to review present procedures to ensure that actions taken are appropriate and timely.

CMS Action:

> **13(a) CMS Enforcement Database.** Complete the development of the CMS CLIA enforcement database to track and monitor labs that necessitate any potential federal enforcement actions.

Conclusion

As you can see, CMS has either taken steps already to address the GAO's recommendations, or is responding to their analysis in a positive manner. We anticipate that the actions we have laid out above will result in continued improvements in our oversight and enforcement of the provisions of CLIA.

I thank the Subcommittee for its time this morning and would be pleased to answer any questions you might have.